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EXAMINER	
ROANE, AARON F	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,342	SPEARS, MICHAEL DOUGLAS	
	Examiner	Art Unit	
	Aaron Roane	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *8 and 9* is/are allowed.

6)☒ Claim(s) *1-7 and 12-20* is/are rejected.

7)☒ Claim(s) *10 and 11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 7, 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamanashi et al. (USPN 6,059,781) in view of Esty et al. (USPN 4,032,738).

Regarding claims 1 and 14, Yamanashi et al disclose a RF generator source (44) connected to an impedance matching circuit (52) comprising an inductive element ("tuning coil" 30) and a conductive cutting tip (24, 26, 38, 40 and/or 43), see col. 4, lines 6-65 and figures 1-7. Yamanashi et al. also disclose that the instrument is used to surgically treat tissue through contact, see abstract. Yamanashi et al. fail to I) explicitly disclose a tuning element, II) disclose a switch electrically connected between the inductive element and the conductive cutting tip and III) disclose encasing the impedance matching circuit in a hand-held probe housing. In regards to the tuning element, it is well known in the art to use tuning elements, in the form of capacitors, in impedance matching circuitry. In fact impedance matching is considered to inherently involve capacitive and

inductive elements. Applicant should refer to the list of references provided in the conclusion of this office action. Additionally, Applicant discloses the conventional approach to impedance or load matching starting on page 8, line 4 and ending on page 9, line 7. Esty et al. disclose an electrosurgical instrument and teach the provision of placing a printed circuit board (31), containing the impedance matching circuitry, within the hand-held housing (10) of the instrument in order to provide low cost elements and techniques as well as a more compact arrangement, see col. 5, lines 29-62. Esty et al. also teach the use of providing the hand-held housing with an electrical switch (11 and 12 or 54 and 55) in order to provide convenient manual use by the surgeon, see abstract and col. 2, lines 16-60. Esty et al. do not disclose the switch connected between the inductive element and the conductive cutting tip, however as is well known in the art facilitates the conduction or non-conduction of treatment energy via the closing or opening of the electrical circuit by the switch. Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Yamanashi et al., as taught by Esty et al., to place a printed circuit board, containing the impedance matching circuitry, within the hand-held housing of the instrument in order to provide low cost elements and techniques as well as a more compact arrangement as well as provide the hand-held housing with an electrical switch in order to provide convenient manual use by the surgeon. Furthermore, at the time of the invention it would have been an obvious matter of design choice to one of ordinary skill in the art to place the switch at any number of places in the treatment energy conducting path or circuit in order to facilitate the conduction or non-conduction of treatment energy via the closing or opening of the

electrical circuit by the switch because Applicant has not disclosed that connecting the switch between the inductive element and the conductive cutting tip provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants invention to perform equally well with the placement of the switch at any number of places in the treatment energy conducting path or circuit because provides the opening and closing of the circuit.

Regarding claim 2, the recitations concerning "the soft electrically-conductive material" and inducing eddy currents are intended use, recitations of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. As a matter of fact, eddy currents are inherently present within the soft electrically-conductive material when impedance matching instruments are used to electrically treat the soft electrically-conductive material. Yamanashi et al. disclose a transformer (30) within the electrically insulated housing, see col. 4, lines 29-33 and figures 5 and 7. Yamanashi et al. do not disclose a cutting tip releasably engagable to said probe housing. Esty et al. teach the use of proving the housing with a "replaceable chuck" (15) such that a wide variety of tips can be used with one instrument, see col. 2, lines 16-42 and figure 1. Yamanashi disclose a housing (18) with an insulative layer, see col. 4 and figures 2-5. And Yamanashi et al. in view of Esty et al. as mentioned in regards to claim 1 above, disclose a switch-contact area encased by probe housing.

Regarding claims 3 and 4, Yamanashi et al. in view of Esty et al. disclose the claimed invention. Yamanashi disclose a metal cylindrically shaped housing (18) with a dielectric layer thereon, see col. 4 and figures 2-5. As mentioned in regards to claim 1, it is known very well in the art that impedance matching inherently involves capacitive elements. It is also well known in the art to use the features of "step-up", "step-down" and center-tapped or multiply-tapped transforming depending on the desired voltage ratio and/or terminals. The flexibility, variability and rearrangement of capacitors, inductors and transformers is well known by one of ordinary skill in the art and demonstrated by the references in the conclusion section of the office action. Yamanashi et al. disclose a tip with the first and second ends located distally and proximally. With the teaching of the "replaceable chuck" by Esty et al. as mentioned in regards to claim 2 above, the second end of said tip is inherently engaged with a release mechanism.

Regarding claim 7, Yamanashi et al. in view of Esty et al. disclose the claimed invention. Esty et al. teach the use of providing the switch with a non-conductive protuberance (22 and 29) (inherently the protuberance is non-conducting), said protuberance having at least one surface (interface of 29 and 30) in contact with a spring-engaged conductive pathway (30), see starting on col. 3, line 66 and ending on col. 5, line 12.

Regarding claim 12, Yamanashi et al. in view of Esty et al. disclose the claimed invention. Using a step-up transformer with the windings wrapped around a magnetic,

iron, or ferrite core is well known in the art and is its motivation can be found in the fact that cores made from these (as well as many others) materials allow for better magnetic or electromagnetic flux coupling of the primary and secondary windings of the transformer which leads to more efficient transformers. As mentioned in regards to claim 1, it is known very well in the art that impedance matching inherently involves capacitive elements. It is also well known in the art to use the features of "step-up", "step-down" and center-tapped or multiply-tapped transforming depending on the desired voltage ratio and/or terminals. The flexibility, variability and rearrangement of capacitors, inductors and transformers is well known by one of ordinary skill in the art and demonstrated by the references in the conclusion section of the office action. Due to the application of the teaching Esty et al. to use a switch and the disclosed features of Yamanashi et al., the switch is located between the secondary winding and the tip. Additionally, the location of the switch (an electrical switch) is almost entirely arbitrary (one should take into account the convenient manipulation of the switch by the operator) and can be placed any where on either the primary winding side or the secondary winding side.

Regarding claim 13, Yamanashi et al. in view of Esty et al. disclose the claimed invention. Yamanashi disclose a metal cylindrically shaped housing (18) with a dielectric layer thereon, see col. 4 and figures 2-5. By Gauss' Law (see any general physics text), any conductive hollow surface provides electromagnetic shielding. Yamanashi et al. disclose a tip with the first and second ends located distally and proximally. With the teaching of the "replaceable chuck" by Esty et al. as mentioned in

regards to claim 2 above, the second end of said tip is inherently engaged with a release mechanism. Finally, Yamanashi et al. provide for the generation of energy with 13.56 or 27. MHz frequencies available, see col. 2, lines 1-15.

Regarding claim 15, Yamanashi et al. in view of Esty et al. disclose the claimed invention. Eddy currents are inherently present within the soft electrically-conductive material when impedance matching instruments are used to electrically treat the soft electrically-conductive material.

Regarding claim 16, Yamanashi et al. in view of Esty et al. disclose the claimed invention. Yamanashi et al. disclose that the instrument is used to surgically treat biological tissue through contact and the conduction of RF energy through the biological tissue using cutting/cauterization, see abstract and col. 2.

Regarding claim 17, Yamanashi et al. in view of Esty et al. disclose the claimed invention. Providing sufficient force to the switch-protuberance such that said conductive-pathway makes contact with said switch-contact area is inherent and is the very nature of operation of electrical switches with spring-engaged conductive pathways.

Therefore it would have been an obvious matter of design choice to one of ordinary skill in the art to

- connect a center-tapped or multiply-tapped transformer, a capacitor and other various electrical elements in a number of different but equivalent ways
- provide the transformer with a particular primary voltage to secondary voltage ratio

because Applicant has not disclosed that

- connecting a capacitor directly to the center-tap of the transformer
- a "step-up" transformer with primary voltage to secondary voltage ratio of 2:1

provides an advantage, is used for some particular purpose, or solves a stated problem. One of ordinary skill, furthermore, would have expected Applicant's invention to perform equally well with connecting a center-tapped or multiply-tapped transformer, a capacitor and other various electrical elements in a number of different but equivalent ways and provide the transformer with a primary voltage to secondary voltage ratio greater or smaller than 2:1 by a few factors. Additionally, it is well known in the art to connect a capacitor to the center tap of a transformer.

Claims 6 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamanashi et al. (USPN 6,059,781) in view of Esty et al. (USPN 4,032,738) as applied to claims 1 and 2 above, and further in view of Eggers (USPN 5,807,392).

Regarding claims 6 and 18, Yamanashi et al. in view of Esty et al. disclose the claimed invention except for providing a cable-release assembly. The spring-engaged switch taught by Esty et al. has a spring assembly which has a surface that is the conductive

pathway and is located between the conductive pathway and the inner surface of the switch casing, see Esty et al., col. 3 and 4 and figure 1. Eggers discloses a coagulation device comprising an impedance matching circuit (149) with the handle or handle portion (22) of the device and teaches the use of providing a releasably connectable cable-release assembly comprising a cable (16) having a connectors (48, 50, 52 and 54). One end of the cable (16) is connected to the treatment device by connectors (52 and 54), while the other end is attached to the generator (14) by connectors (48 and 50). The cable release assembly is comprised of the connectors (52 and 54) at the distal end of the cable (16) and opposing engaging connectors (125 and 126) located in the proximal end of the handle or handle portion (22), see col. 7 and 8, col. 12, lines 25-41and col. 13, lines 10-26 and figures 1, 3 and 4. The steps engaging a cable to the cable-release assembly or mechanism to connect the RF source is inherent. Similarly the step of releasably engaging the second end portion of said tip to the distal end of said probe is inherently embodied by system comprising the "replaceable chuck" disclosed by Esty et al. as mentioned in regards to claim 2 above. It is well known in the art that these cable-release assemblies are provided in order to allow for further interchanging capabilities of the generator with various probes, more convenient and compact storage and greater flexibility when replacing parts (i.e., one may only need to replace a bad probe, while the generator and cable are fine).

Claims 5, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamanashi et al. (USPN 6,059,781) in view of Esty et al. (USPN 4,032,738) as applied to claims 1 and 14 above, and further in view of Anderson et al. (USPN 4,607,161).

Regarding claims 5 and 19, Yamanashi et al. in view of Esty et al. disclose the claimed invention except for providing an optical switch, a fiber optic and a photodectector. Anderson et al. disclose a fiber optic switch system and teach the use of an optical switch (16), an optical fiber (15) and a photodetector (44). The motivations for this optical switch provision are well known in the art and include avoiding electrical point bounce, electrical contact resistance, electrical short, mechanical failure as well as expense. By Gauss' Law (see any general physics text), any conductive hollow surface provides electromagnetic shielding. Therefore, the hollow metallic probe (18) provides EM shielding. Additionally, Yamanashi disclose a metal cylindrically shaped housing (18) with an insulative dielectric layer thereon, see col. 4 and figures 2-5. Esty et al. also disclose that the "replaceable chuck" (15) is an insulating body, see col. 3, lines 25-47. In regards to the conduction of current through the tuning element, the inductive element, the impedance matching circuit, the tip and the biological tissue, the devices and methods of Yamanashi et al. and Esty et al. inherently involve this conducting current. Also the step of making contact with the tissue is inherent. Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Yamanashi et al. in view of Esty et al., as taught by Anderson et al. and as is well known in the art, to use of an optical switch, an optical fiber and a photodetector in order to avoid electrical point bounce, electrical contact resistance, electrical short, mechanical failure and expense inherently involved with electrical/mechanical switches.

Regarding claim 20, Yamanashi et al. in view of Esty et al. and in further view of Anderson et al. disclose the claimed invention. In regards to the conduction of current through the tuning element, the inductive element, the impedance matching circuit, the tip and the biological tissue or material, the devices and methods of Yamanashi et al. and Esty et al. inherently involve this conducting current. Also the step of making contact with the tissue is inherent. Eddy currents are inherently present within the soft electrically-conductive material when impedance matching instruments are used to electrically treat the soft electrically-conductive material.

Allowable Subject Matter

Claims 8 and 9 are allowed.

Claims 10 and11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Amendment

The Affidavit filed on 7/3/2003 under 37 CFR 1.131 is sufficient to overcome the Eggers (USPN 5,911,719) reference. A new and earlier reference (also an Eggers reference) Eggers (USPN 5,807,392) was applied.

The examiner acknowledges the drawings are indeed sufficient, has withdrawn the previous objection and thanks Applicant for pointing out the oversight. The amendments to the specification are noted as are the minor amendments to claims 1, 2,14 and 20. The amendment to claim 8 has been significant and has placed claims 8 and 9 in allowable form.

Beginning on page 10, line 20 Applicant asserts the following:

First Applicant argues that the Yamanashi et al. reference sole disclosure or suggestion of an electrosurgical instrument lies in a reference to an earlier Yamanashi et al. reference (USPN 5,019,076) where Applicant cites col. 4, lines 42-52 of primary reference used in the initial office, Yamanashi et al. (USPN 6,059,781). Then applicant goes on to describe how the disclosure of Applicant, see page 1, line 33 through page 2, line 23 distinguishes itself over the USPN 5,019,076 Yamanashi et al. reference. The main point here being that Yamanashi et al. disclose an on/off foot switch, wherein Applicant goes on to preference and advantages of switch located on the device handle over that of a foot switch. The examiner addresses these points forthwith.

The primary reference used for the rejection was Yamanashi et al. (USPN 6,059,781). Applicant is correct in stating that Yamanashi et al. (USPN 6,059,781) references the earlier Yamanashi et al. (USPN 5,019,076) reference in col. 4, lines 42-52 of Yamanashi et al. (USPN 6,059,781). However, the reference in col. 4, lines 42-52 of Yamanashi et al. (USPN 6,059,781)

is not to the electrosurgical instruments but to the components of the electrical circuitry shown in figures 6 and 7 of Yamanashi et al. (USPN 6,059,781). Yamanashi et al. (USPN 6,059,781) makes no claim of the electrosurgical tool of Yamanashi et al. (USPN 5,019,076) nor does Yamanashi et al. (USPN 6,059,781) make reference to a foot pedal of any kind or a switch of any kind. As to the preference and advantages of switch located on the device handle over that of a foot switch, the examiner believes this to be a matter of personal preference or a matter of practicality when one operator is responsible for the operation of an electrosurgical instrument with many button/switch controllable functions. This switch/pedal preference is supported by a large amount of prior art.

Applicant then goes on to state that "there is no reason identified or suggested by Yamanashi et al. .... to arrive at Applicant's claimed combination," on page 11, lines 35-37. If Yamanashi et al. (USPN 6,059,781) identified or suggested reasons for arriving at Applicant's claimed combination, a 35 U.S.C. 102(b) rejection would have been made. As stated above in the 103(a) rejection over Yamanashi et al. (USPN 6,059,781) in view of Esty et al. (USPN 4,032,738), Yamanashi et al. fail to I) explicitly disclose a "tuning element", II) disclose a switch electrically connected between the inductive element and the conductive cutting tip and III) disclose encasing the impedance matching circuit in a hand-held probe housing. In regards to the tuning element, it is well known in the art to use tuning elements, in the form of capacitors, in impedance matching circuitry. In fact impedance matching is considered to inherently involve capacitive and inductive elements. Applicant should refer to the list of references provided in the conclusion of this office action. Additionally, Applicant discloses the conventional approach to

impedance or load matching which involves capacitive and inductive elements starting on page 8, line 4 and ending on page 9, line 7. Secondly, the placement of a switch on the device handle is shown by the secondary reference, Esty et al. "for convenient manual use," see abstract and col. 2, lines 16-60. Third, it is extremely well known in the art to provide a an electrical activation switch on the handle of an electrosurgical device as is the equivalence between switches in the device handle or exterior foot pedal switched. Fourth, the issue of the switch not being explicitly shown electrically connected between the inductive element and the conductive cutting tip is an issue of design choice and one of ordinary skill in the art, furthermore, would have expected Applicants invention to perform equally well with the placement of the switch at any number of places in the treatment energy conducting path or circuit because provides the opening and closing of the circuit. Finally, Esty et al. teach the provision of placing a printed circuit board (31), containing the impedance matching circuitry, within the hand-held housing (10) of the instrument in order to provide low cost elements and techniques as well as a more compact arrangement, see col. 5, lines 29-62.

Applicant assertion that the motivation and teachings of the Yamanashi et al. and Esty et al. references is unpersuasive.

Regarding the remarks concerning the combination of the above references with Eggers (USPN 5,911,719), the examiner acknowledges the lack of a proper prior effective date in light of the filed affidavit. The examiner has provided an earlier Eggers (USPN 5,807,392) that teaches further interchanging capabilities of the generator with various probes, more convenient

and compact storage and greater flexibility when replacing parts (i.e., one may only need to replace a bad probe, while the generator and cable are fine) by providing a cable-release assembly an explicitly detailing the cable release mechanism.

Finally, Applicant's basic argument with the use of the Anderson et al. (USPN 4,607,161) reference is that it is narrow in scope and does not suggest the use of the fiber optic switch in electrosurgical instrumentation, see page 13, lines 1-13. Claims 5, 19 and 20 are directed in part to the specific matter of optical switches, therefore proper examination of these claims requires the review and possible application of prior art directed to the specifics of optical switches. Additionally, Anderson not only teaches the use of optical switches , it also teaches the advantages of optical switches over electrical or mechanical switches. Finally, Anderson et al. is directed to fiber optics and it discloses that fiber optics is widely used in the medical field, see col. 1, lines 12-20.

The examiner acknowledges and has fully considered the amendments and remarks. The rejections are maintained and reaffirmed. This rejection is final.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (703) 305-7377. The examiner can normally be reached on 9am - 5pm, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

A.R. A.R.
September 26, 2003

Roy D. Gibson
ROY D. GIBSON
PRIMARY EXAMINER